DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 00D–1681]

Guidance on Use of Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies." This guidance updates a notice of availability entitled "Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use" published in the **Federal Register** on June 29, 1982, concerning the prophylactic use of potassium iodide (KI) in the event of release of radioactive isotopes of iodine. In this guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland and, thus, reduce the risk of thyroid cancer in the event of a radiation emergency. The guidance recommends lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

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Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rose Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6779.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Emergency Management Agency (FEMA) has established roles and responsibilities for Federal agencies in assisting State and local governments in their radiological emergency planning and preparedness activities. The Federal agencies, including the Department of Health and Human Services (DHHS), are intended to accomplish these roles and responsibilities as part of the Federal Radiological Preparedness Coordinating Committee. Among other responsibilities, DHHS is to provide guidance on the use of radioprotective substances to reduce radiation doses to specific organs from the release into the environment of large quantities of radioactivity. FDA is specifically charged with providing guidance on the prophylactic use of KI in the event of release of radioactive isotopes of iodine.

As part of its responsibilities as established by FEMA, on June 29, 1982, FDA published in **the Federal Register** a notice entitled "Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use" (47 FR 28158). In that notice, the agency made recommendations regarding the use of KI as a thyroid blocking agent. During 1999 to 2000, the agency reviewed additional data gathered primarily after the Chernobyl reactor accident. On January 4, 2001 (66 FR 801), the agency issued a draft guidance that revised some of the 1982 recommendations. The initial comment period on the draft guidance closed on February 5, 2001. On February 9, 2001 (66 FR 9711), the agency extended the comment period to April 30, 2001. After consideration of all comments, the agency is issuing this final version of the guidance. Other than clarifying edits, the agency has made no substantial changes to the recommendations

incorporated in the draft guidance. In this guidance the agency maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland and thus to reduce the risk of thyroid cancer in the event of a radiation emergency. FDA proposes lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended. FDA's revised recommendations are in general accordance with those of the World Health Organization, as expressed in its "Guidelines for Iodine Phrophylaxis Following Nuclear Accidents" (1999), except for minor modifications.

The recommendations in the guidance were prepared by FDA scientists from the Center for Drug Evaluation and Research and from the Center for Devices and Radiological Health, in consultation with other governmental experts.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the use of potassium iodide as a thyroid blocking agent in radiation emergencies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm **or** http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 12/3/01

December 3, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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